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| APPLICATION NO.                     | FILING DATE                  |            | FIRST NAMED INVENTOR  |   | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|-------------------------------------|------------------------------|------------|-----------------------|---|-------------------------|------------------|
| 09/784,645                          | 02/15/2001                   |            | Stephen A. Empedocles |   | 019916-001210US         | 5563             |
| 20350                               | 7590                         | 11/29/2001 |                       | , |                         |                  |
| TOWNSEN                             | D AND TO                     | WNSEND A   | EXAMINER              |   |                         |                  |
| TWO EMBARCADERO CENTER EIGHTH FLOOR |                              |            |                       |   | FORMAN, BETTY J         |                  |
| SAN FRANC                           | SAN FRANCISCO, CA 94111-3834 |            |                       |   | ART UNIT                | PAPER NUMBER     |
|                                     |                              |            |                       |   | 1655                    | _                |
|                                     |                              |            |                       |   | DATE MAILED: 11/29/2001 | 8                |

Please find below and/or attached an Office communication concerning this application or proceeding.

|  | Application No.  | Applicant(s)   |  |  |  |  |  |
|--|--|--|--|--|--|--|--|
|  | 09/784,645   | EMPEDOCLES ET AL.  |  |  |  |  |  |
| Office Action Summary  | Examiner   | Art Unit   |  |  |  |  |  |
| ,  | BJ Forman  | 1655   |  |  |  |  |  |
| The MAILING DATE of this communication ap  |  |  |  |  |  |  |  |
| Period for Reply   | •  |  |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPL<br>THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a replif NO period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by status. Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).  Status | .136(a). In no event, however, may<br>ply within the statutory minimum of t<br>d will apply and will expire SIX (6) M<br>te. cause the application to become | a reply be timely filed thirty (30) days will be considered timely. IONTHS from the mailing date of this communication. ABANDONED (35 U.S.C. § 133). |  |  |  |  |  |
| 1) Responsive to communication(s) filed on 15  | February 2001 .  |  |  |  |  |  |  |
| 2a) ☐ This action is <b>FINAL</b> . 2b) ☑ T  | his action is non-final.   |  |  |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.   |  |  |  |  |  |  |  |
| Disposition of Claims  |  |  |  |  |  |  |  |
| 4) Claim(s) 1-43 is/are pending in the application   | n.   |  |  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdra   | awn from consideration.  |  |  |  |  |  |  |
| 5) Claim(s) is/are allowed.  |  |  |  |  |  |  |  |
| 6)  Claim(s) is/are rejected.  |  |  |  |  |  |  |  |
| 7) Claim(s) is/are objected to.  |  |  |  |  |  |  |  |
| 8) Claim(s) <u>1-43</u> are subject to restriction and/or  | election requirement.  |  |  |  |  |  |  |
| Application Papers   |  |  |  |  |  |  |  |
| 9) The specification is objected to by the Examiner.   |  |  |  |  |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ acce  | epted or b) objected to b  | y the Examiner.  |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |  |  |  |  |  |  |  |
| 11) The proposed drawing correction filed on   | _ is: a)∏ approved b)[   | disapproved by the Examiner.   |  |  |  |  |  |
| If approved, corrected drawings are required in reply to this Office action.   |  |  |  |  |  |  |  |
| 12)☐ The oath or declaration is objected to by the E   | xaminer.   |  |  |  |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120  |  |  |  |  |  |  |  |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  |  |  |  |  |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:   |  |  |  |  |  |  |  |
| 1. Certified copies of the priority documer  | nts have been received.  |  |  |  |  |  |  |
| 2. Certified copies of the priority documer  | nts have been received in  | Application No   |  |  |  |  |  |
| 3. Copies of the certified copies of the prication from the International B  * See the attached detailed Office action for a lis   | lureau (PCT Rule 17.2(a)   | <b>)).</b>   |  |  |  |  |  |
| 14) Acknowledgment is made of a claim for domes  | •  |  |  |  |  |  |  |
| a) ☐ The translation of the foreign language provisional application has been received.  |  |  |  |  |  |  |  |
| 15) Acknowledgment is made of a claim for domes  |  |  |  |  |  |  |  |
| Attachment(s)  |  |  |  |  |  |  |  |
| <ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449) Paper No(s)</li> </ol>   | 5) Notice  | ew Summary (PTO-413) Paper No(s)<br>of Informal Patent Application (PTO-152)   |  |  |  |  |  |

Application/Control Number: 09/784,645

Art Unit: 1655

## **Election/Restrictions**

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-26 and 40-43, drawn to a method of detecting a ligand, classified in class 435, subclass 4.
  - II. Claims 27-31, drawn to an analytical method, classified in class 435, subclass6.
  - III. Claims 32-39, drawn to an analytical method, classified in class 435, subclass4.
- 2. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and III are independent and distinct methods. Inventions are independent and distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and they have different modes of operation and different functions i.e. the method of Invention I operates by contacting an array of immobilized antiligands with a sample and functions to detect a ligand from the sample; the method of Invention II operates by contacting an array of immobilized primers with a sample and extending the primers and functions to identify extended primers; and the method of Invention III operates by contacting ligand-antiligand binary complexes with a second antiligand and functions to identify ternary complexes.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Art Unit: 1655

## **Election of Species**

4. This application contains claims directed to multiple patentably distinct species of the claimed invention. Invention I contains claims directed to the primary species (i.e. antiligand) and the primary species contains multiple subspecies (i.e. nucleic acids, proteins) which contains further multiple subspecies and son on. Invention III contains claims directed to the primary species (i.e. antiligand) which contains multiple subspecies (i.e. nucleic acids, proteins, antibodies) which contain further multiple subspecies and son on.

Applicant is required under 35 U.S.C. 121 to elect **a single disclosed species** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

5. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEM § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence of identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 (a) of the other invention.

6. A telephone call was made to Mr. Scott Ausenhus on 27 November 2001 to request an oral election to the above restriction requirement, but Mr. Ausenhus was unavailable to make an election and it was requested that a written Restriction be mailed.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

## Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:45 TO 4:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D. November 27, 2001

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